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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,665	08/07/2003	Hiraku Murayama	029650-144	8895

21839 7590 11/27/2006

BUCHANAN, INGERSOLL & ROONEY PC  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

EXAMINER
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HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/635,665	Applicant(s) MURAYAMA ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-21 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/2006 has been entered.

### ***Response to Amendment***

2. The affidavit filed under 37 CFR 1.132 filed 10/10/2006 is insufficient to overcome the rejection of claims 1 and 16-20 based upon 35 USC 102(b) as being anticipated by Uchino et al (US 6,001,068) as set forth in the last Office action because: although Uchino et al discloses a super elastic alloy comprising a first wire, Uchino et al discloses plastically deforming the first super elastic alloy wire such that the original shape is *substantially* retained (column 11 lines 45-53). Thus, Uchino et al discloses a first super elastic alloy wire that after undergoing plastic deformation may not retain its original shape. In addition, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

***Notice of Amendment***

3. In response to the amendment filed on 10/10/2006, amended claim(s) 1 and 13-15 and new claims 24-27 is/are acknowledged. The previous rejections of claims 1-3 and 12-21 and 23 are withdrawn. The following new and reiterated grounds of rejection are set forth:

***Specification***

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Uchino et al (US 6,001,068). Uchino discloses a guidewire (1), comprising:

- a distally disposed reshapeable (as in the case of plastic deformation positively recited in column 11 lines 45-53) metal first wire (A) capable of being plastically deformed to maintain a desired shape;

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- a proximally disposed pseudo-elastic alloy second wire (B) (column 4 line 1);
- wherein said first and second wires have a common longitudinal axis and are joined by spot or butt-resistance welding the first wires proximal end face to the second wires distal end face (column 7 lines 19-67 and column 8 lines 16-22) as best seen in Figures 1-3;
- wherein the connection end faces of wires A and B are nearly perpendicular to the axial direction of both wires A and B (column 7 lines 5-19);
- wherein the welded portion is located proximal the proximal end of a spiral coil (112) covering at least a distal end portion of wire A as best seen in Figure 1, 9, 12, 14, and 17; and
- wherein a fixing material (113) is fixed to a distal end of the spiral coil and a distal end of the first wire.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2, 12, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Jansen (US 5,365,943). Uchino et al discloses the claimed guidewire, as aforementioned, except for a third wire member proximally disposed to the second and the third member having a larger elastic modulus than the second. Jansen teaches a guidewire, comprising: three wire members (proximal 44, intermediate 46, and distal 48 regions) each having a different flexibility or elastic modulus (column 4 lines 25-63), wherein the proximal member has the largest elastic modulus, stainless steel for example (column 6 lines 42-44) and the distal member has the smallest. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Uchino et al, with the third wire member as taught by Jansen for the purpose of configuring the mechanical properties (i.e. flexibility, elastic modulus, etc...) of a guidewire for navigating tortuous vasculature.

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Abrams et al (US 5,341,818). Uchino et al discloses the claimed guidewire except for a taper of the guidewire extending from a region proximal the welded region of the proximal wire to a region distal the welded region of the distal wire. Abrams shows in Figure 1 a taper of a guidewire extending from a proximal region across a joint

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to the distal region. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Uchino et al, with the taper as taught by Abrams for the purpose of configuring the mechanical properties (i.e. flexibility, elastic modulus, etc...) of a guidewire for navigating tortuous vasculature.

11. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al. Uchino et al discloses the claimed invention but does not disclose expressly the first wire ranging in length from 10 to 1,000 mm. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the first wire of the guidewire as taught by Uchino et al with the claimed length range, because Applicant has not disclosed that disclosed length provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the distal most wire as taught by Uchino et al, because it configures the distal region of a guidewire for navigating tortuous vasculature and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Uchino et al. Therefore, it would have been an obvious matter of design choice to modify Uchino et al to obtain the invention as specified in the claim(s).

12. Claims 21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Palermo et al (US 5,769,796). Uchino et al discloses the claimed guidewire except for the welded portion between first and second wires located distal the proximal end of the spiral coil. Palermo et al teaches configuring a guidewire (100) such that the welded portion (128) is located distal the proximal end of a spiral coil (112)

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as best seen in Figure 5A. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Uchino et al, with Palermo et al for the purpose of configuring the mechanical properties (i.e. flexibility, elastic modulus, etc...) of a guidewire for navigating tortuous vasculature.

### ***Response to Arguments***

13. Applicant's arguments filed 10/10/2006 have been fully considered but they are not persuasive. Applicant argues (a) Uchino et al is not configured to be plastically deformed and (b) there is no motivation to combine the welded coil as taught by Uchino et al with Palermo et al because Uchino et al does not disclose an end cap.

14. In response to applicant's argument (a) that Uchino et al is not configured to be plastically deformed, Uchino et al discloses plastically deforming the first super elastic alloy wire such that the original shape is *substantially* retained (column 11 lines 45-53) and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

15. In response to applicant's argument (b) there is no motivation to combine the welded coil as taught by Uchino et al with Palermo et al because Uchino et al does not disclose an end cap. Examiner disagrees and maintains as broadly as structurally claimed claims 21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Palermo et al because Palermo et al teaches



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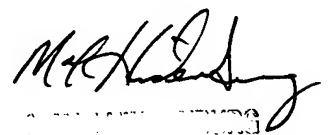
configuring a guidewire (100) such that the welded portion (128) is located distal the proximal end of a spiral coil (112) as best seen in Figure 5A.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JEFFREY G. HOEKSTRA  
Examiner  
Art Unit 3736

JH

